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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,052	03/24/2004	Richard S. Blumberg	18989-033	4208

30623 7590 11/16/2005

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER	
KOSAR, ANDREW D	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,052	BLUMBERG, RICHARD S.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *9-15,33,34,38,39,47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,16-23,34-37,40-46,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20051107* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply Sequences/RAW sequence listing.

DETAILED ACTION

Sequence Compliance

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821- 1.825) in order to effect a complete response to this office action.

As described on the attached "Raw Sequence Listing Error Report", Applicant's submitted sequence listing/CRF of June 15, 2005 is defective and a corrected diskette is required.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm>, EFS Submission User Manual – ePave)

2. US Postal Service:
Commissioner for Patents
PO Box 22313-1450
Alexandria, VA 22313-1450

3. Hand carry, Federal Express, United Parcel Service, or other delivery service:
U.S. Patent and Trademark Office
Mail Stop Sequence
Customer Window, Randolph Building
401 Dulany Street
Alexandria, VA 22314

Election/Restrictions

Applicant's election without traverse of Group VI, and the species where n=1, P is $C(O)NHCH_2CF_3$ and Q is piperidine in the reply filed on August 26, 2005 is acknowledged.

As noted in the attached Interview summary with Applicant's representative, Ms. Ingrid Beattie, on November 8, 2005, claims 24 and 25 were properly indicated as members of Group VII but were inadvertently indicated as also being linking claims in the restriction requirement. Claims 24 and 25 would not be examined as linking claims, and be withdrawn from consideration as drawn to a nonelected invention (Group VII), which would be rejoined upon indication of allowable linking claims. Applicant reaffirmed the election of Group VI and the species indicated *supra*.

Claims 9-15, 24-33, 38, 39, 47 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 26, 2005.

Claims 1-8, 16-23, 34-37, 40-46, 49 and 50 are have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites inhibiting inflammation by administering 'to an inflamed tissue'. It is unclear how one could 'inhibit inflammation' in an 'inflamed tissue' because if the tissue is already inflamed, one is treating inflammation and not inhibiting inflammation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 16-23, 34-37, 40-46, 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by GREGG (WO 98/50028 A1).

The instant claims are generally drawn to inhibition of inflammation, inhibition of CD1-mediated inflammation, and inhibition of tissue inflammation.

Gregg teaches the elected species, identified as BMS-201,238 in a pharmaceutical composition (claim 10, page 47). It is noted by the examiner that BMS-201,<u>0</u>38 (page 27), is the same compound by structure, and is claimed in a pharmaceutical composition (claim 21, page 55), and is identified in the specification as a 'most preferred' compound for practicing the invention (page 27).

Gregg teaches a method of lowering serum lipid levels, cholesterol and/or triglycerides, inhibiting and/or treating hyperlipidemia, hyperlipemia, hyperlipoproteinemia, hypercholesterolemia and/or hypertriglyceridemia, and/or preventing, inhibiting or treating atherosclerosis, pancreatitis, hyperglycemia or obesity in a mammalian species, comprising administering the compounds of claim 1 to a patient in need in a therapeutically effective amount (claims 22 and 23).

Atherosclerosis and diabetes (hyperglycemia) are art recognized to have inflammatory components (e.g. REGAN-US Patent 6,080,763, column 3, lines 3-5; SALZMAN- US PGPUB 2001/0053763 A1, page 3, [0040]).

Gregg further teaches that the oral doses of the drug are 0.01 mg/kg to about 100 mg/kg, but preferably from 0.1 mg/kg to 75 mg/kg, and parenteral administration being preferred at 0.005 mg/ to about 8 mg/kg. (page 34). Additionally, it is noted that cardiac inflammation 'includes' atherosclerosis (page 18, instant specification).

Because the claims are drawn to 'inhibiting' / 'inhibition', the broadest reasonable interpretation of the claims embraces prevention of the diseases, and as such, administration of the compound to <u>any</u> patient in the 'effective doses' as instantly disclosed inherently effects the instantly claimed result, e.g. inhibiting colitis, neurological inflammation, etc. If one were to administer the compound to any patient in the instantly disclosed dosages, one would not experience inflammation ('inhibit inflammation') and one would inherently be inhibiting production of an inflammatory cytokine.

Because the compounds are administered to a patient and the preferred compound administered is the elected species, and the effective doses of Gregg are those which are instantly

disclosed as the therapeutic doses (e.g. instant specification, page 19, lines 14-15 "An effective amount...is preferably from about 0.1 mg/kg to about 150 mg/kg.") the claims are anticipated.

Conclusion

NO CLAIMS ARE ALLOWED.

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Art Unit 1654

CHRISTOPHER R. TATE
PRIMARY EXAMINER

Notice to Comply	Application No. 10/808,052	Applicant(s) BLUMBERG, RICHARD S.	
	Examiner Andrew D. Kosar	Art Unit 1654	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☒ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
Technical Assistance..703-287-0200
To Purchase PatentIn Software.........................703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

BEST AVAILABLE COPY

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/808,052B
Source: IFW16
Date Processed by STIC: 6-21-05

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail
Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom
Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses.

1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05): U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05

IFW16

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RAW SEQUENCE LISTING                              DATE: 06/21/2005
PATENT APPLICATION:  US/10/808,052B                TIME: 10:53:24

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 7 <130> FILE REFERENCE: 18989-033
 9 <140> CURRENT APPLICATION NUMBER: 10/808,052B
10 <141> CURRENT FILING DATE: 2004-03-24
12 <150> PRIOR APPLICATION NUMBER: 60/457,048
13 <151> PRIOR FILING DATE: 2003-03-24
15 <160> NUMBER OF SEQ ID NOS: 16
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Does Not Comply
Corrected Diskette Needed
(pg.1-3)

ERRORED SEQUENCES

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     604     130                 135                 140
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     607 145                 150                 155                 160
     609 Ile Ser Ala Leu Leu Val Pro Pro Glu Xaa Glu Glu Ala Lys Gln Xaa
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PATENT APPLICATION: US/10/808,052B TIME: 10:53:24

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See error explanation on pg. 1.

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                    PATENT APPLICATION:  US/10/808,052B      TIME: 10:53:24

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pls delete

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